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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,583	05/10/2006	Christa Schleper	009848-0324026	2702

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EXAMINER	
MARVICH, MARIA	

ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,583	SCHLEPER ET AL.	
	Examiner	Art Unit	
	MARIA MARVICH	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *6/30/10*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,8-15 and 21* is/are rejected.

7)☒ Claim(s) *5, 7, 16,-19, 22 and 23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 June 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/12/11 has been entered.

Claims 1-3 and 5-23 are pending. Claim 20 is an improper multiple dependent claims that do not refer to the claims in the alternative, e.g. claim 1 and 14 are both required in one alternative. Hence, claim 20 has been withdrawn from examination. See MPEP § 608.01(n).

Claim Objections

Claims 1, 3, 6, 8, 11, 14, 15, 17-19, 21 and 23 are objected to because of the following informalities: **These are objections maintained from the office action mailed 9/14/11.**

The recommendation made in the rejection mailed 9/14/10 stands wherein it is proper to recite in claim 1, line 4, -- a coding sequences for a site-specific integrase --.

Hence, in claim 3 the reference to "said origin of replication" does not indicate which of the two are recited. As well, when referring to previous limitations, the word "said" is used when the reference uses the terms as previously recited in exact terms. In this case, "said" is used improperly in claim 3 when referring to "said genes encoding the structural proteins".

Claim 8 formatting is improper in that the groups are recited as if the promoters are all of the promoters from 16S, 23S rRNA or all of those form polymerases, transcription, replication or

translation factors. It would be remedial to recite, --a promoter of the ribosomal subunit 16s, a promoter of ribosomal subunit 23s, a polymerase promoter, a transcription promoter, a replication promoter or a translation factor promoter--.

The comma following "a reporter protein" in claim 11 is grammatically incorrect.

The recitation in claim 14, "is E. coli or sulfolobus" is grammatically incorrect. As well, E. coli should be italicized. The claim should recite, --is *E. coli* or a *sulfolobus* cell.

Claim 15 is unclear. Claim 15 recites that "the transformed expression vector provides a gene encoding an essential protein". It is unclear if this is the same essential protein as that in claim 1. If so then the claim is redundant as claim 1 already recites that the gene is in the vector. As well, it is not clear how a vector can "provide" a gene. If it is the same as that in claim 1, claim 15 should be deleted. If it is an additional gene than the claim should be amended to recite --wherein the expression vector of claim 14 has an gene encoding a second essential protein--.

In claim 17 the phrase "(poly)peptide" is inconsistent with previous recitations.

Applicants argue that the phrase is not vague nor indefinite. However, the recitation "said (poly)peptide is not supported by the claim. The claim previously recites polypeptide whereas (poly)peptide implies that the structure can be a peptide or a polypeptide. This is not supported by the claim.

In claim 18 the article "a" is required in line 2 prior to SSV1 and SSV2 and the article "the' prior to SSV2 in step (a) and prior to SSV1 and SSV2 in step (b).

These are new objections.

Claim 6 recites that the vector has a promoter for expression of the gene of interest, whereas the vector of claim 1 already comprises a promoter for expression of the gene of interest.

In claim 19, "a gene of interest" is improper and should be –the gene of interest--. When referring to limitations previously recited, it is proper to use the article "the".

Claim 21 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Both claims are drawn to the same essential protein from sulfolobus.

In claim 23 it is not clear how sequences 3' of the gene of interest can be an N-terminal extension. The specification actually states that the vector comprises 3' to the translation initiation site of the promoter additional nucleic acid sequences that are the N-terminal extension.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 6, 8, 10, 14, 15 and 21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. **This rejection is maintained for reasons**

of record in the office action mailed 2/3/10 and 9/14/10 and restated below. The claims, as written, do not sufficiently distinguish over cells that exist naturally because the claims do not particularly point out any non-naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206, USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor , e.g. by insertion of "Isolated" or "Purified" . Specifically, the vector of claims 1-3, 5, 6, 8, 10, 14, 15, 21 and 22 reads on natural SSV1, SSV2, pSSVx and pRN.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 8-10, 11-15 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Stedman et al Genetics **152:** 1397–1405 (August 1999). **This rejection is maintained for reasons of record in the office action mailed 2/3/10 and restated below.**

Stedman et al teach a vector that comprises the SSV1 genome and hence inherently comprises each of an ori, genes encoding the structural proteins and site-specific integrase from SSV1 each operably linked to expression control sequences. As well, the vector comprise essential genes encoding for example aminoacid biosynthesis genes (see figure 1). Furthermore, the vector has been modified with restriction sites that are flanked by expression control

sequences of for example e178 (see figure 5). However, the vector will have natural restriction sites that are found within range of natural promoters. SSV1 comprises a number of promoters for example Tind is inducible by IV irradiation (see e.g. 1401, col 1, ¶ 2). However a number of the promoters (see e.g. figure 5) are constitutive. In figure 5 is a shuttle vector that further comprises an E. coli origin of replication as well as a variant of a reporter gene and a marker.

Response to Amendment.

Applicants argue that SSV1 is an organism distinct from sulfolobus. As well, applicants argue that the vector of Stedman et al does not disclose an SSV1 expression vector with any non-viral genes let alone one or more selectable markers encoding an essential protein for Sulfolobus nor introduction thereof. However, applicants throughout the claims and the specification refer to both the virus and the cell with equivalent terms. Specifically, the claims recite for example, a sulfolobus origin of replication and in claim 2 wherein the sulfolobus origin of replication is from SSV1 or SSV2. It is not clear why this reference to sulfolobus can mean SSV1 or SSV2 and yet other references to sulfolobus essential proteins cannot embrace this same meaning. Applicants argue that the definition of the essential protein is to a cellular protein. However, the following definition is present in the specification. While, the sulfobulos proteins are preferred, there is no explicit definition limiting the proteins to those from the cell and not the virus.

[0017] In yet another preferred embodiment of the invention, the selectable marker gene of the expression vector encodes an essential protein of Sulfolobus. In a more preferred embodiment of the present invention, the essential gene is a gene of the de novo nucleotide anabolism, a gene of the aminoacid biosynthesis or a gene conferring antibiotic resistance. In another more preferred embodiment, the vector contains orotidine-5'-monophosphatase pyrophosphorlyase and orotidine-5'-monophosphatase decarboxylase (pyrEF) as selectable marker genes (Martusewitsch et al. 2000).

In interpreting the claims, the broadest reasonable interpretation must be used. In this case, there is no distinction in the claims or in the specification for those components that are based in the virus and those that are based in the cell. However, applicants would wish for some distinction solely based upon arguments. In other words, by reference to sulfolobus, the claims suggest that either the virus or the cell is involved. Applicants cannot pick one interpretation over the other as both interpretation s are valid when considering the full scope of the claims. Secondly, the arguments that the construct of Stedman et al does not require an introduced gene or a gene of interest is outside of the scope of the claims which only require that the vector be capable of accepting a gene of interest. All vectors such as viral vectors are capable of carrying heterologous genes as well accepting sequence for transfer. There is no reason to believe that SSV1 cannot do so also.

As to the rejection under 35 USC 101, as the vector *as claimed* reads on a naturally occurring SSV1 vector, the claim reads on a naturally occurring sequence.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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